CHAPTER 1

REGULATORY ORGANIZATION

The purpose of this chapter is to provide an overview of the organizational structure and directory of the offices involved in compliance related functions within the Food and Drug Administration (FDA).

This chapter contains the following sections:

1-10 INTRODUCTION

The purpose of this chapter is to provide an overview of the organizational structure of the offices involved in compliance related functions within FDA. It is not the intent to provide a complete description of FDA's organizational structure. FDA's functional statement for each office may be found in various chapters of FDA's Staff Manual Guide (SMG). This guide is available on FDA's Intranet Website.

This Regulatory Procedures Manual (RPM) chapter is divided into sections based on major organizational units, and includes a section for all Centers and the Office of Regulatory Affairs (ORA). An "Enforcement Policy Directory" is available on FDA's Internet Website at http://www.fda.gov/ora/compliance_ref/rpm/.

1-20 OFFICE OF REGULATORY AFFAIRS (ORA)

ASSOCIATE COMMISSIONER FOR REGULATORY AFFAIRS (ACRA)

ORA is under the direction of the Associate Commissioner for Regulatory Affairs, Mr. John M. Taylor. The functional statements for ORA are:

- Advises and assists the Commissioner and other key officials on regulations and compliance-oriented matters that have an impact on policy development and execution and long-range program goals.
- Coordinates, interprets, and evaluates the Agency's overall compliance efforts; as necessary, establishes compliance policy or recommends policy to the Commissioner.
- Stimulates an awareness within the Agency of the need for prompt and positive action to assure compliance by regulated industries; works to assure an effective and uniform balance between voluntary and regulatory compliance and Agency responsiveness to consumer needs.

- Evaluates and coordinates all proposed legal actions to ascertain compliance with regulatory policy and enforcement objectives.
- Executes direct line authority over all Agency field operations; develops, issues, approves, or clears proposals and instructions affecting field activities; serves as the central point within the Agency through which Headquarters offices obtain field support services.
- Provides direction and counsel to Regional Food and Drug Directors (RFDDs) in the implementation of policies and operational guidelines that form the framework for management of Agency field activities.
- Develops and/or recommends to the Commissioner policy, programs, and plans for activities between the Agency and state and local agencies; administers the Agency's overall Federal-State program and policy; coordinates the program aspects of Agency contracts with state and local counterpart agencies.
- Evaluates the overall management and capabilities of the Agency's field organization; initiates action to improve the management of field activities and coordinates the formulation and management of career development plans.
- Directs and coordinates the Agency's emergency preparedness and civil defense programs.
- Operates the Federal Medical Products Quality Assurance Program for the Agency.

OFFICE OF ENFORCEMENT (HFC-200)

The functional statements for the Office of Enforcement are:

- Advises and assists the Associate Commissioner and other key officials on regulations and compliance matters that impact on policy development, implementation, and long-range program goals.
- Coordinates, interprets, and evaluates the Agency's overall compliance efforts; as necessary, establishes compliance policy and recommends policy to the Associate Commissioner.
- Stimulates an awareness within the Agency of the need for prompt and positive action to assure compliance by regulated industries; works to assure an effective and uniform balance between regulatory compliance and Agency responsiveness to consumer needs.
- Acts as liaison with other federal agencies on Agency compliance matters and encourages an effective and appropriate balance between voluntary and regulatory compliance.
- Evaluates and coordinates proposed legal actions to ascertain compliance with regulatory policy and enforcement objectives.
- Directs and coordinates with the Office of Regional Operations (ORO), other Agency components, and Office of Chief Counsel (OCC), new or novel cases which may be precedent-setting.
- Resolves appeals when proposed compliance actions are disapproved by the Centers or OCC.
- Coordinates development of the Agency wide bioresearch monitoring activities; monitors compliance activities to assure uniform application of compliance policy; serves as liaison with other federal agencies and outside organizations relating to such Agency wide activities.
- Serves as the Agency focal point for activities relating to the Federal Medical Products Quality Assurance Program and maintains liaison with other government agencies procuring medical supplies; issues final administrative approval for quality assurance of specific products/firms.

There are three divisions within the Office of Enforcement:

Division of Compliance Management and Operations
Division of Compliance Policy
Division of Compliance Information and Quality Assurance

DIVISION OF COMPLIANCE MANAGEMENT AND OPERATIONS (HFC-210)

The functional statements for the Division of Compliance Management and Operations are:

- Performs final administrative review of proposed legal actions for sufficiency of evidence and coordinates the acquisition of additional evidence needed through the appropriate Centers and the field offices.
- Resolves disputes or other problems encountered during case review to assure that Agency decisions are consistent.
- Provides guidance for and participates in the development of new, novel, or precedent-setting cases. Provides counsel to the field on compliance matters. Interprets policy and major action decisions and provides guidance on their application.
- Evaluates terminated legal cases to determine effectiveness in bringing about correction and to evaluate enforcement strategies and evidentiary and other problems. Performs trend analysis and identifies actual and potential problem areas. Advises Agency regarding actions initiated through case news digest.
- Participates in the design and implementation of training programs for Headquarters and field compliance personnel.
- Serves as the Agency clearance point and coordinator for all warrants, both administrative and search and seizure.
- Serves as the Agency focal point for guidance on recall plans and procedures. Directs and coordinates field activities in support of all product recalls. Maintains liaison with other Agency components, industry, and other government agencies to ensure proper implementation and completion of recall plans and activities.

DIVISION OF COMPLIANCE POLICY (HFC-230)

The functional statements for the Division of Compliance Policy are:

- Develops, coordinates, and monitors the development of new or modified Agency compliance policies and regulatory procedures for all domestic and imported products regulated by the Agency. Directs and coordinates the preparation and maintenance of compliance type publications including the Compliance Policy Guides Manual, the Regulatory Procedures Manual, and the Enforcement Story.
- Reviews all Agency planned regulatory initiatives associated with the regulatory planning process to determine the need for an enforcement strategy. Reviews, initiatives and makes recommendations to the Director, Office of Enforcement, concerning the adequacy of enforcement strategies.
- Serves as the Agency focal point with other governmental agencies including foreign, other federal agencies and state agencies for information on compliance policies and regulatory procedures. Coordinates requests from other federal agencies such as the FTC, SEC and USDA for assistance or information. Develops policy and coordinates handling of requests for testimony of Agency employees from foreign governments, other federal agencies, state and

local government agencies, and private litigation attorneys and recommends Agency response.
- Provides policy and program direction to Agency units carrying out the objectives of the Bioresearch Monitoring Program (BMP). Coordinates assignments involving multiple FDA Centers and interagency inspectional assignments. Monitors compliance activities to assure uniform application of compliance policy and monitors Agency performance in meeting program accomplishment projections for the BMP. Evaluates proposed disqualification recommendations of clinical investigators, institutional review boards, and toxicology laboratories.
- Serves as the Agency focal point for resolving intra-agency enforcement policy issues at the Headquarters level and for Headquarters/field operational and compliance relations on Agency compliance policy.
- Serves as the focal point for coordinating the Freedom of Information (FOI) activities within ORA. Prepares responses to FOI requests. Develops guidelines for the field and coordinates field implementation of provisions for the Privacy Act and FOI Act.
- Develops and coordinates the content and preparation of the CD-ROM information Data Base (ORA CD-ROM Gold Disc).

DIVISION OF COMPLIANCE INFORMATION AND QUALITY ASSURANCE (HFC-240)

The functional statements for the Division of Compliance Information and Quality Assurance are:
- Develops and maintains liaison with other government agencies procuring medical products; develops and maintains operational agreements and systems; serves as the FDA focal point for all activities relating to the government-wide quality assurance program.
- Receives and processes requests from other federal agencies for quality assurance support; serves as the final administrative approval authority for quality assurance evaluations of specific products and firms; provides quality assurance evaluation responses to requesting agencies.
- Maintains liaison, coordinates, and directs field and Headquarters activities relating to the government-wide quality assurance program.
- Monitors the Agency's Field Accomplishments and Compliance Tracking System (FACTS).
- Manages the Agency’s program for providing quality assurance information to state and foreign governments in support of their procurements or determinations of admissibility of U.S. products.
- Publishes the FDA Gold Disk and Eureka Disk.
- Coordinates policy development on electronic records and electronic recordkeeping.
- Manages the Agency’s Turbo Establishment Inspection Report (EIR) system.

ORA FIELD ORGANIZATION

The ORA field organization is divided into regional offices. The regional offices are under the direction of Regional Food and Drug Directors (RFDDs) who report to the ACRA. There are five regional offices. They are located as follows:

1.	Northeast Region	Jamaica, NY
2.	Central Region	Philadelphia, PA
3.	Southeast Region	Atlanta, GA
4.	Southwest Region	Dallas, TX
5.	Pacific Region	Oakland, CA

There are two to seven district offices within each region for a total of 19 districts. Each district office

is usually comprised of three to four branches, including either a Compliance Branch or an Enforcement Branch, which is the primary regulatory contact within a district office.

1-30 CENTER FOR BIOLOGICS EVALUATION AND RESEARCH (CBER)

OFFICE OF COMPLIANCE AND BIOLOGICS QUALITY (HFM-600)

The functional statements for the Office of Compliance and Biologics Quality are:

- Monitors the quality of marketed biological products through surveillance, inspections, and compliance programs, and coordinates testing of marketed products with other components of the FDA.
- Identifies and recommends appropriate action, in coordination with other CBER/Agency components, on the results of continuing surveillance and evaluation of advertising and clinical experience reports submitted by manufacturers and sponsors of products regulated by the Center.
- Develops policies and procedures, receives, reviews, evaluates, and takes appropriate action on establishment license applications submitted by manufacturers (except blood and plasma establishments) in coordination with other CBER components, and establishes written and reference standards for biological products establishments (except blood and plasma establishments).
- Advises the Center Director and other Agency officials on emerging and significant compliance issues for biological products and serves as CBER's focal point for surveillance and enforcement policy.
- Coordinates CBER's participation in the inspection of biological product manufacturing facilities.
- Develops, with other CBER/Agency components, compliance standards for biological products, including Current Good Manufacturing Practice (CGMP) regulations, ensures their uniform interpretation and evaluates industry's conformance with CGMP in manufacturing biological products.
- Directs CBER's bioresearch monitoring program, enforcement, and recall programs for biological products.
- Except for programs relating to consumer affairs activities, develops biological product compliance and surveillance programs, coordinates and directs their field implementation, and advises other CBER components on these programs.
- Provides guidance to Headquarters and field personnel in the development of evidence to support enforcement actions.
- Coordinates all CBER-field compliance activities, including planning and field assignments.
- Coordinates CBER's import and export programs.
- In coordination with other CBER components, responsible for lot release of biological products including testing products and review of protocols submitted for release by manufacturers. Also maintains a reference reagent program.
- Reviews, and evaluates all administrative action recommendations including suspension, revocation, denial of license, debarment, disqualification of clinical investigators, and recommended civil and criminal actions, including seizure, injunction, and prosecution based on findings of inspections and investigations.
- Coordinates CBER's application integrity policy.
- In coordination with other Agency components, formulates policy in the areas of compliance and biologics quality including enforcement, good manufacturing practices, and labeling including

advertising and promotion, and drafts guidance documents for other Agency components and regulated industry on these subjects including documents regarding error and accident reporting, content and format of chemistry, manufacturing and controls information and establishment information, and container closure systems for packaging of human drugs and biologics.
- Reviews and enforces regulations pertaining to product labeling including proprietary names, labels, package inserts, and promotion and advertising material. Formulates and establishes policy for the regulation of promotional activities including advertisements, promotional labeling, and promotional practices.
- Plans and develops, in coordination with other Agency and CBER components, information and education activities related to labeling and advertising approval for health professionals, consumers, and Agency staff.

The Office of Compliance and Biologics Quality is including the two Divisions:

Division of Case Management
Division of Inspections and Surveillance

DIVISION OF CASE MANAGEMENT (HFM-610)

The functional statements for the Division of Case Management are:
- Reviews and evaluates administrative action recommendations including suspension, revocation, denial of license and debarment. Reviews recommended civil and criminal actions, including seizure, injunction, and prosecution. Prepares documents required for such enforcement actions and manages cases after actions are taken.
- Coordinates support for ongoing litigation and contested cases with the Office of Chief Counsel and the Department of Justice, including the identification and preparation of expert witnesses.
- In coordination with the Office of Communications, Training, and Manufacturers Assistance, provides training for CBER and other Agency personnel regarding evidence development in support of administrative and legal actions.
- Provides primary support within the Office of Compliance and Biologics Quality for Agency Ad Hoc Committee Meetings relating to proposed enforcement action against products, manufacturers or other individuals associated with CBER regulated products.
- Develops enforcement standards for direct reference authority to FDA district offices for issuance of Warning Letters and reviews and evaluates Team Biologics and district generated recommendations for the issuance of Warning Letters for which direct reference authority had not been granted.
- Coordinates CBER's application integrity policy.
- Directs and coordinates CBER's review of applications for export of unapproved biological products.
- Provides assessment of the compliance status of regulated firms within CBER's purview (compliance status checks).
- Reviews, evaluates, and monitors material associated with promotion, advertising, conferences, exhibits, and similar types of media for all biological products, new drugs, and medical devices approved by CBER. Participates in actions to remedy violative promotion.
- Serves as the focal point within CBER for voluntary and FDA requested recalls including tissue recall orders.
- Coordinates the review and evaluation of requests from manufacturers for the release of plasma

derivatives manufactured from blood and blood components subject to recall.

DIVISION OF INSPECTIONS AND SURVEILLANCE (HFM-650)

The functional statements for the Division of Inspections and Surveillance are:

- Coordinates and provides support and guidance to district offices for investigations and surveillance inspections.
- Works with the Office of Regulatory Affairs (ORA) to prepare inspection work plans and allocate resources for the biological product inspection program.
- Develops guidance and other training programs in conjunction with CBER components, to promote industry compliance and for use in training Headquarters and field inspection staffs.
- Develops and updates compliance programs on behalf of CBER.
- Manages the biological compliance surveillance activities including review of transfusion-related fatality reports.
- Plans and directs investigation and surveillance assignments in response to reports regarding product defects, adverse events, error and accident reports, and allegations of violative activity. Evaluates the related inspection and investigation reports, and recommends enforcement action when necessary.
- Manages the Bioresearch Monitoring programs for CBER, including clinical investigator disqualifications. Reviews and evaluates Establishment Inspection Reports and prepares Warning Letters.
- Coordinates Office follow-up and response to complaints related to investigational products and clinical trials.
- Working with the Office of Communications, Training, and Manufacturers Assistance, provides guidance to industry and government concerning bioresearch monitoring policies and regulations.
- Manages CBER's emergency and product shortage programs.
- Promotes uniformity between CBER and ORA with regard to conducting inspections and the implementation of Current Good Manufacturing Practices (CGMPs) policy.
- Serves as CBER's contact for Team Biologics issues during inspections.
- Supports the CBER pre-approval inspection program.
- Serves as the CBER contact for other federal agencies concerning enforcement matters, and coordinates review of these matters with other Agency components as appropriate.

1-40 CENTER FOR DRUG EVALUATION AND RESEARCH (CDER)

OFFICE OF THE CENTER DIRECTOR (HFD-1)

The functional statements for the Office of Center Director are:

- Promulgates, plans, administers, coordinates, and evaluates overall Center scientific, management, and regulatory programs, plans, and policies.
- Provides leadership and direction for all Center activities.
- Coordinates and directs the Center management, planning, and evaluation systems, to assure optimum utilization of Center manpower, financial resources, and facilities.

OFFICE OF MEDICAL POLICY (HFD-40)

The functional statements for the Office of Medical Policy are:

- Develops medical policy regarding the evaluation of new drug applications (NDA's) and drug development, jointly with the Office of Review Management, oversees development of guidance related to medical policy, generally with participation of the Medical Policy Coordinating Committee, and in consultation with other coordinating committees and offices as appropriate; establishes and maintains medical policy liaison with Congress and other outside groups; spearheads the Good Review Practices (GRPs) initiative including guidelines, Standard Operation Procedures, etc. Schedules and supports the Refusal to File and Clinical Hold Committee meetings.
- Monitors and regulates promotional activities of the prescription drug industry and researches drug information communication channels.
- Initiates necessary actions to maintain industry compliance with prescription drug advertising and labeling regulations.
- Oversee the activities of the Division of Scientific Investigations and with the Division of Marketing, Advertising and Communications and Office of Review Management, develops policy for these activities.

The Office of Medical Policy is including the two Divisions:

Division of Marketing, Advertising and Communications
Division of Scientific Investigations

DIVISION OF MARKETING, ADVERTISING AND COMMUNICATIONS (HFD-40)

The functional statements for the Division of Marketing, Advertising and Communications are:

- Monitors and evaluates prescription drug promotions, advertising, conferences, exhibits, and similar types of media.
- Formulates and establishes policy for the regulation of prescription drug promotions, including advertisements, promotional labeling, and promotional practices.
- Initiates or recommends administrative action to remedy violative prescription drug promotions, initiates field investigations, and assists in the preparation of prospective cases.
- Plans and supervises studies which evaluate the impact of health communication and prescription drug promotions to both professionals and consumers and evaluates compliance actions for violations of prescription drug promotion regulations.
- Plans and develops, in coordination with other Agency and Center components, information and educational resources for health professionals, consumers, and Agency staff, including a drug labeling manual, miscellaneous publications, symposia, and seminars.

DIVISION OF SCIENTIFIC INVESTIGATIONS (HFD-340)

The functional statements for the Division of Scientific Investigations are:

- Develops and implements the Agency's Bioresearch Monitoring Program for Human Drugs and Narcotic Addiction Treatment Monitoring Programs under the Federal Food, Drug, and Cosmetic Act (the Act), the Public Health Service Act, and other federal statutes, and applicable regulations.

- Develops standards for the conduct of clinical and preclinical investigations performed to demonstrate the safety and effectiveness of drug products.
- Designs and operates surveillance and compliance programs in the areas of preclinical and clinical drug products investigations, bioequivalence studies, human subject protection, and narcotic addiction treatment programs.
- Assigns, directs and coordinates onsite inspections of sponsors and investigators of preclinical and clinical drug product studies, bioequivalence, biopharmacokinetics, and biopharmacodynamic studies and the laboratories used for these studies, institutional review committees, and commercial clinical testing facilities in collaboration with the Agency's field organization. Evaluates investigation reports and initiates administrative and regulatory corrective measures as necessary.
- Recommends approval, denial of approval, or revocation of approval of programs that use methadone and other drugs for which treatment standards have been promulgated; assigns and directs inspections of such programs to determine compliance with standards and regulations; and takes appropriate action when such activities are not in compliance with regulations.

OFFICE OF COMPLIANCE (HFD-300)

The functional statements for the Office of Compliance are:

- Monitors the quality of marketed drugs through product testing, surveillance, and compliance programs.
- Advises the Center Director and other Agency officials on FDA's regulatory responsibilities for drugs.
- Directs and coordinates Center regulation-writing activities.
- Develops standards for drug industry practices, including Current Good Manufacturing Practice (CGMP) regulations, and ensures their uniform interpretation.
- Directs the Center's bioresearch monitoring program for drug products.
- Identifies problems in drug regulation, manufacturing, and quality assurance and conducts voluntary compliance programs and studies.
- Develops drug quality assurance compliance and surveillance programs; coordinates and directs their field implementation; and advises other Center components on these programs.
- Coordinates Center-field relations, provides support and guidance to the field on legal actions, case development and contested cases, and reviews and decides disposition of field submissions involving deviations from standards.
- Recommends approval, denial of approval, or revocation of approval of activities that use methadone and other drugs for which treatment standards have been promulgated, taking any appropriate compliance action.
- Evaluates, in coordination with appropriate Agency regulatory affairs officials, a firm's conformance with CGMP in producing drugs for procurement by federal and state agencies.
- Evaluates, classifies, and recommends drug recalls and provides Center coordination with field recall activities.

There are three divisions under the Office of Compliance:

Division of Labeling and Nonprescription Drug Compliance
Division of Manufacturing and Product Quality
Division of Prescription Drug Compliance and Surveillance

DIVISION OF LABELING AND NON-PRESCRIPTION DRUG COMPLIANCE (HFD-310)

The Division, which was formerly the Division of Drug Labeling Compliance, has replaced branches with three teams. They are the OTC Compliance Team, the Nontraditional Drugs Compliance Team and the Import/Export International Drug Compliance Team. The teams receive technical guidance from the team leaders and management direction from the Division Director and Deputy Director.

The Health Fraud Staff, which was formerly located in the immediate Office of the Director, is now the Nontraditional Drugs Compliance Team. The new name reflects the changing attitudes toward alternative medicine in the Administration, an increasing role in regulating homeopathic drugs, and the management of complex regulatory issues, such as the Dietary Supplement Health and Education Act, counterfeit drugs and Non-Prescription Drug Marketing Act diversion.

DIVISION OF MANUFACTURING AND PRODUCT QUALITY (HFD-320)

The functional statements for the Division of Manufacturing and Product Quality are:

- Develops and directs Center drug product quality enforcement programs. Develops Agency compliance policy for enforcement of the law regarding drug product quality.
- Processes regulatory actions involving drug product quality requirements, and supports litigation arising from regulatory actions.
- Serves as Agency focal point regarding compliance of establishments and products with current good manufacturing practices (CGMPs) and other drug product quality requirements of the law.
- Develops guidance materials and educational programs to promote compliance with drug product requirements.

DIVISION OF PRESCRIPTION DRUG COMPLIANCE AND SURVEILLANCE (HFD-330)

The primary responsibility of the division includes the enforcement of the new drug and misbranding provisions of the Federal Food, Drug, and Cosmetic Act (the Act) for prescription drugs; the monitoring of the quality of the nation's drug supply through postmarketing surveillance activities and processing regulatory actions and supporting litigation involving new drug and misbranding issues.

Responsibilities include:

- Developing policies and compliance strategies to ensure marketed prescription drugs are legally labeled.
- Identifying the compliance status of all currently marketed drugs and taking appropriate action to ensure the safety and effectiveness of the nation's drug supply.
- Supporting HCFA by providing them with the effectiveness status of drugs thereby precluding the reimbursement of less-than-effective prescription drugs.
- Developing policies and compliance strategies for regulating prescription drugs prepared/manipulated by state-licensed and non-licensed establishments.
- Monitoring and evaluating drug product quality through the Drug Quality Reporting System.
- Coordinating with other Center components to exchange drug quality data and advising them on drug quality evaluation programs.
- Monitoring the quality of the nation's drug supply through postmarketing surveillance sampling of foreign and domestic finished dosage forms and bulk pharmaceutical chemicals.

- Monitoring the Adverse Drug Experience Program to assure the safety of marketed drugs and industry compliance with the regulations.
- Enforcing the NDA Field Alert regulations to assure applicants are adhering to the timely reporting requirements and reviewing compliance actions, submitted by the field, for failure to meet these requirements.
- Determining the effectiveness of tamper-resistant packaging (TRP) for over-the-counter drugs.
- Preventing the diversion of counterfeit, subpotent, adulterated, and misbranded prescription drug products by administering the Prescription Drug Marketing Act (PDMA).
- Assuring the quality of insulin and oral digoxin tablets in the marketplace through certification programs.

1-50 CENTER FOR DEVICES AND RADIOLOGICAL HEALTH (CDRH)

OFFICE OF COMPLIANCE (HFZ-300)

The Office of Compliance (OC) develops, directs, coordinates, evaluates, and monitors compliance programs covering regulated industry. OC conducts field tests and inspections when necessary for regulatory purposes, evaluates industry quality control and testing programs to assure compliance with regulations, and provides advice to Agency field offices on, and manages Center activities relating to, legal actions, case development, and contested case assistance, and coordinates all field planning activities and issues all field assignments for the Center.

There are five divisions in the Office of Compliance:

Division of Bioresearch Monitoring
Division of Program Operations
Division of Enforcement I
Division of Enforcement II
Division of Enforcement III

DIVISION OF PROGRAM OPERATIONS (HFZ-305)

The functional statements for the Division of Program Operations are:

- Advises and supports Office officials and staff regarding all policies and procedures relating to administrative support activities.
- Advises Office officials and staff regarding management information system initiatives and serves as the Office liaison to other Center and Agency components on all such matters. Plans, coordinates, and implements office automation within the Office.
- Provides information for requests from external as well as internal sources. Coordinates and processes Freedom of Information Requests (FOI) and issues certificates for requests to export approved medical devices and non-approved medical devices under 801(e) of the Federal Food, Drug, and Cosmetic Act (the Act).
- Coordinates the Center's administrative activities with field offices as well as internal regulatory actions.
- Develops, coordinates, and/or conducts medical device and electronic products training programs for field personnel and state and local agencies in coordination with other Center and Agency components.

- Develops, processes information for, and maintains the medical device registration and product listing system; develops and monitors contracts for data processing; ensures industry compliance with reporting requirements through a certification program; and develops and maintains a document tracking system.

There are two branches within this division:

Field Programs Branch
Information Processing and Office Automation Branch

DIVISION OF BIORESEARCH MONITORING (HFZ-310)

The functional statements for the Division of Bioresearch Monitoring are:

- Enforces the Medical Device Amendments of 1976 and the Safe Medical Devices Acts of 1990 and 1992 as they relate to investigational devices.
- Manages and coordinates the administrative and regulatory responsibilities of the Agency's Bioresearch Monitoring Program for medical devices. Prepares related Warning Letters and other correspondence. Ensures corrective actions taken by firms inspected under the Bioresearch Monitoring Compliance Program are acceptable.
- Assigns, directs, and coordinates on-site inspections of sponsors and investigators of preclinical and clinical device product studies, institutional review boards, commercial clinical testing facilities, and nonclinical toxicology laboratories in collaboration with the Agency's field organization.
- Provides regulatory guidance and interpretations of the informed consent, institutional review board, and the investigational device exemption regulations to the field and industry.
- Designs, implements, and evaluates surveillance and compliance programs in the areas of preclinical and clinical investigational device product investigations. Manages the premarket approval data audit program to ensure the integrity of data submitted to the Agency.
- Coordinates and implements the Agency's Application Integrity Policy for medical devices.

There are two branches within the Division of Bioresearch Monitoring (HFZ-310):

Program Enforcement Branch I
Program Enforcement Branch II

DIVISION OF ENFORCEMENT I (HFZ-320)

Enforces medical device regulations as they relate to in vitro diagnostics, diagnostic devices, and general surgery devices.

There are three branches within this division:

In Vitro Diagnostic Branch
Diagnostic Devices Branch
General Surgical Devices Branch

DIVISION OF ENFORCEMENT II (HFZ-330)

Enforces medical device regulations as they relate to dental; ear, nose, and throat (ENI); ophthalmic; urology, gastroenterology; general hospital; obstetrics/gynecology (OB/GYN); and therapeutic radiographic devices.

There are three branches within this division:

Dental, ENT, and Ophthalmic Devices Branch
OB/GYN, Gastroenterology, Urology Devices Branch
General Hospital and Therapeutic Radiographic Devices Branch

DIVISION OF ENFORCEMENT III (HFZ-340)

Enforces medical device regulations as they relate to cardiovascular, therapeutic radiologic, orthopedic, physical medicine, anesthesiology, and neurology devices.

There are three branches within this division:

Cardiovascular and Neurological Devices Branch
Orthopedic, Physical Medicine, and Anesthesiology Devices Branch
Electronic Products Devices Branch

The functional statements for the Divisions of Enforcement I, II, and III, as they relate to each division's specialty areas, are:

- Manages and coordinates activities associated with administrative and regulatory actions.
- Develops, interprets, and issues policy guidance in response to specific requests from the medical device and electronic product industries, trade associations, other federal agencies, other countries, state agencies, and the general public. Develops, reviews, and revises new and amended regulations including good manufacturing practices (GMPs) and standards for electronic products.
- Plans, initiates, coordinates, and conducts medical device and electronic product inspections and investigations of manufacturers and their products. Reviews and evaluates design, test, and production data and reports from manufacturers to ensure compliance with promulgated standards and regulations.
- Identifies the need for and directs the development of compliance policy guides and programs to facilitate compliance by manufacturers. Develops, coordinates, reviews, and revises medical device industry GMP regulations. Develops and implements programs to ensure uniform interpretation and application of GMPs and recommends regulatory action when appropriate.

1-60 CENTER FOR FOOD SAFETY AND APPLIED NUTRITION (CFSAN)

OFFICE OF FIELD PROGRAMS (HFS-600)

The functional statements for the Office of Field Programs are:

- Serves as the focal point between the Center and the field.

- Coordinates with Center program offices and the Office of Regional Operations in developing and implementing field programs. Evaluates field accomplishments and provides feedback to Center and field management.
- Reviews proposed recalls and regulatory actions for adequacy of evidence and consistency across programs; and coordinates with and refers cases to the appropriate program offices for policy and technical review.
- Plans and develops approaches to implement regulatory responsibilities in interstate travel sanitation.
- Publishes and promotes sanitation standards for regulating food service, food stores, and food vending operations and the milk industry. Provides information, training, and technical assistance to implement such standards.
- Coordinates with the states on the National Shellfish Sanitation Program and evaluates state programs.
- Conducts a national certification program for laboratories testing dairy products and other foods.
- Develops and supports the implementation of Hazard Analysis Critical Control Point (HACCP) programs in the production and processing of foods. Provides technical evaluations to support regulation of low-acid, thermally processed foods.

There are three divisions within the Office of Field Programs:

Division of Enforcement and Programs
Division of HACCP Programs
Division of Cooperative Programs

DIVISION OF ENFORCEMENT AND PROGRAMS (HFS-605)

The functional statements for the Division of Enforcement and Programs are:

- Evaluates and recommends solutions to compliance problems involving foods, cosmetics, pesticides, and food chemicals.
- Reviews proposed recalls and regulatory actions for adequacy of evidence and consistency across programs; and coordinates with and refers cases to the appropriate program offices for policy and technical review.
- Develops and maintains procedures when authority for direct case handling has been delegated to the field.
- Manages the development of controversial, precedent-setting, and contested court cases and provides guidance and technical support as necessary.
- Provides oversight for the field (ORA) Food and Cosmetics Program accomplishments.
- Coordinates with the CFSAN program offices, compliance programs and assignments for the implementation by the field. Acts as liaison with ORA to assure that CFSAN's program proposals are acceptable and reflect current policy.
- Monitors and summarizes field accomplishments to effect correction or completion of activities and provides feedback to the CFSAN program offices, Center management, and ORA. Identifies trends in monitoring and compliance efforts to redirect resources to problem areas.
- Develops the CFSAN recommendations regarding field resource utilization, needs, and reallocation proposals; training; and program priorities in order to accomplish high priority CFSAN activities. Prepares the field resource allocation for the CFSAN programs.
- Maintains liaison with the Field Food Committee.

There are three branches within the Division of Enforcement and Programs:

Imports Branch
Case Processing Branch
Domestic Branch

DIVISION OF HACCP PROGRAMS (HFS-615)

The functional statements for the Division of HACCP Programs are:

- Establishes FDA Hazard Analysis Critical Control Point (HACCP) concepts and policy regarding HACCP programs.
- Develops model/generic HACCP systems and plans, implements HACCP pilot programs in conjunction with the food industry and/or trade associations.
- Coordinates FDA field and/or industry HACCP initiatives and systems.
- Conducts a national certification program for state laboratories testing dairy products and other foods.
- Standardizes, evaluates and certifies state and territorial milk laboratory evaluation officers.
- Provides consultation to FDA, and outside organizations on laboratory equipment, apparatus, methods, and facilities problems associated with laboratory examination of foods.
- Conducts and/or participates in the preparation of FDA and/or state milk and food seminars, conferences, workshops, and training courses on laboratory methodology.
- Supports the low-acid canned food (LACF) regulations by filing, reviewing, and registering LACF processes.
- Provides technical evaluation of thermal processing equipment and potential public health sterilization process delivery problems and deviations from LACF regulations. Recommends regulatory action when appropriate.

There are two branches within this division:

Laboratory Quality Assurance Branch
Regulatory Food Processing & Technology Branch

DIVISION OF COOPERATIVE PROGRAMS (HFS-625)

The functional statements for the Division of Cooperative Programs are:

- Promotes sanitation standards in the form of model ordinances for regulating food service, food storage and food vending operations, shellfish, and the milk industry.
- Cooperates with health industry standards writing groups that produce milk and food equipment design and construction standards.
- Provides information, training, and technical assistance to Agency and outside organizations on code interpretation, compliance procedures, and problem solving to maintain uniform Agency-developed standards of sanitation for the retail food and milk industries.
- Plans and coordinates, with ORA, field activities relating to the accomplishment of compliance program requirements, decisions on requests for special investigations, and the planning and surveillance of food operations in federally-managed locations.
- Coordinates with the states on the National Shellfish Sanitation Program and evaluates state

programs.
- Plans and develops approaches to implement regulatory responsibilities in interstate travel sanitation.

There are three branches within this division:

Milk Safety Branch
Retail Food Protection Branch
Shellfish Program Implementation Branch

OFFICE OF COSMETICS AND COLORS (OCAC) (HFS-100)

DIVISION OF PROGRAMS AND ENFORCEMENT POLICY (HFS-105)

- Develops regulations, compliance policy, position papers, regulatory guidelines, and advisory opinions on issues related to cosmetic ingredients and products, color additive certification, color additive diluents, and products containing color additives.
- Reviews proposed regulatory actions referred by the Office of Field Programs for program policy consideration and provides technical evaluation on cases related to this Office.
- Serves as the Agency focal point for the development and evaluation of programs and the implementation of the laws and regulations related to this Office.
- Manages the review of petitions and evaluates and prepares the necessary action on petitions submitted to the Agency related to the functions of this Office.
- Administers the Agency's Color Certification and Cosmetic Registration Programs.

There are two branches within this division:

Cosmetics Programs and Regulations Branch
Color Certification Branch

OFFICE OF NUTRITIONAL PRODUCTS, LABELING AND DIETARY SUPPLEMENTS (ONPLDS) (HFS-800)
DIVISION OF COMPLIANCE AND ENFORCEMENT (HFS-810)

- Develops compliance strategies, regulatory guidance and enforcement policies related to the scope of responsibility of the Office.
- Provides support and guidance to the field, in cooperation with the Office of Field Programs, in handling regulatory actions and provides Headquarters assistance in the development, management, and coordination of cases related to the responsibilities of this Office. Reviews proposed regulatory actions referred by the Office of Field Programs, and provides technical evaluations on cases related to the responsibilities of this Office.
- Serves as the principle Agency liaison for implementation of the laws and regulations related to the responsibilities of this Office. Provides regulatory guidance and assistance to federal and state agencies and industry concerning regulatory requirements and compliance policies.
- Evaluates the use of structure/function claims and recommends action.
- Reviews food product labeling for adherence to regulations; reviews nutrient composition/content information to determine the accuracy of manufacturers' claims.
- Serves as the principle Agency liaison for the development and evaluation of compliance

programs related to this Office and participates in programs designed to improve compliance by industry.
- Provides expert advice and assistance to the Center Director, other key officials, and the field on field programs, compliance and enforcement issues, and related activities within the scope of responsibilities of the Office.
- Responds to requests for Certificates of Export (Certificates of Free Sale) with respect to food labeling and to specific products that are the responsibility of this Office.

There are two branches within this division:

Dietary Supplements Branch
Conventional Foods and Special Nutritionals Branch

OFFICE OF PLANT AND DAIRY FOODS AND BEVERAGES (OPDFB) (HFS-300)

DIVISION OF PLANT PRODUCT SAFETY (HFS-305)

- Develops, collects, and interprets data regarding the safety, composition, quality, and manufacture of plant and plant products, bottled water, and miscellaneous products.
- Develops policy, regulations, position papers, regulatory guidelines, compliance strategies, and advisory opinions on issues related to plant and plant product safety.
- Provides expert policy, scientific and technical advice, and assistance to the Center Director, other key officials, and the field on plant product safety issues, field programs, initiatives, and other related activities.
- Reviews proposed regulatory actions referred by the Office of Field Programs for policy consideration and provides technical evaluation and necessary scientific support on cases related to plant and plant product issues.
- Reviews petitions on plant and plant product issues related to this Office.
- Serves as the Agency focal point for the development and evaluation of programs and the implementation of the laws and regulations related to this Office regarding plant and plant products, bottled water, and other miscellaneous issues.

DIVISION OF RISK ASSESSMENT (HFS-355)

- Develops the Center for Food Safety and Applied Nutrition's (CFSAN's) monitoring/surveillance programs for pesticide residues, industrial chemicals, toxic elements, and natural toxins in foods.
- Serves as CFSAN's resource for technical information on Agency monitoring programs and data regarding pesticide residues, industrial chemicals, process induced toxicants, toxic elements, and natural toxins in foods.
- Proposes, develops, and manages research initiatives for toxicological studies that will serve the needs of the Office's programs mandates.
- Provides toxicological evaluations related to the presence of industrial chemicals, process induced toxicants, toxic elements, and natural toxins in foods.
- Develops new risk assessment methodologies for risk assessments particularly in the area of dose-response assessment of industrial chemicals, process induced, toxic elements and natural toxins in foods.

- Provides safety and quantitative risk assessments on industrial chemicals, process induced toxicants, toxic elements, and natural toxins in foods.
- Provides toxicological evaluations and risk assessments on a consultative basis for other program offices.

DIVISION OF DAIRY AND EGG SAFETY (HFS-365)

- Develops, collects, and interprets data regarding the safety, composition and quality of eggs, manufacture of dairy products, and food products containing dairy or egg ingredients.
- Develops policy, regulations, position papers, regulatory guidelines, compliance strategies and policies, and advisory opinions on issues related to the safety of milk, eggs, and derived products.
- Provides expert policy, scientific, and technical advice and assistance to the Center Director, other key officials, and the field on dairy and egg safety issues, field programs, initiatives, and other related activities.
- Reviews proposed regulatory actions referred by the Office of Field Programs for program policy considerations and provides technical evaluation and necessary scientific support on cases related to milk and egg issues.
- Reviews petitions on milk and egg issues related to this Office.
- Serves as the Agency focal point for the development and evaluation of programs and the implementation of the laws and regulations related to this Office regarding dairy, egg, game meat, and other miscellaneous issues.

OFFICE OF SEAFOOD (OS) (HFS-400)

DIVISION OF PROGRAMS AND ENFORCEMENT POLICY (HFS-415)

- Develops regulations, compliance policy, position papers, regulatory guidelines, and advisory opinions on issues related to seafood.
- Reviews proposed regulatory actions referred by the Office of Field Programs for program policy consideration and provides technical evaluations on cases related to this Office.
- Serves as the Agency focal point for the development and evaluation of programs, for the development of Agency seafood resource allocation recommendations, and the implementation of the laws and regulations related to this Office.
- Reviews petitions for implementing action levels set by this Office.

There are two branches within this division:

Policy Guidance Branch
Programs and Enforcement Branch

1-70 CENTER FOR VETERINARY MEDICINE (CVM)

OFFICE OF SURVEILLANCE AND COMPLIANCE (HFV-200)

The functional statements for the Office of Surveillance and Compliance are:

- Advises the Center Director on surveillance and compliance policy concerning FDA regulatory

responsibility with respect to animal drugs, feeds, feed additives, veterinary medical devices, and other veterinary medical products.
- Develops and evaluates surveillance and monitoring programs to ensure the safety and effectiveness of animal drugs, and to detect emerging resistance to antimicrobials among zoonotic enteric pathogens.
- Plans, develops, monitors, and evaluates Center surveillance and compliance programs and coordinates their field implementation to ensure the safety and effectiveness of marketed animal drugs, feeds, feed additives, veterinary medical devices, and other veterinary medical products.
- Directs and coordinates the development of scientific evidence supporting Formal Evidentiary Hearings requested by the Center.
- Recommends to the Center Director the amendment or withdrawal of approved new animal drugs applications.
- Develops, coordinates, and directs the Center's Voluntary Bioresearch Monitoring Program to ensure reliability of information on which to base new animal drug and food additive approvals.
- Provides epidemiology expertise to the Center as needed.

The three divisions in this Office are:

Division of Surveillance
Division of Animal Feeds
Division of Compliance

DIVISION OF SURVEILLANCE (HFV-210)

The functional statements for the Division of Surveillance are:
- Evaluates the safety and effectiveness of marketed animal drugs, special dietary feeds, veterinary medical devices, and other veterinary medical products and recommends action to correct deficiencies resulting from inadequate directions for use, warnings, and cautionary information.
- Evaluates drug product labels and other information to determine new animal drug status, regulatory priority, acceptable conditions of use, and need for regulatory activity. Maintains and makes available inventory listings of all marketed animal drugs to ensure adequate information is available for regulatory activity and customer support. Coordinates with field to develop enforcement activity, obtains expert witnesses and performs other scientific and regulatory case development activities.
- Reviews marketed product labeling and makes recommendations concerning label revisions, regulatory supplements, suspension of manufacturing, and withdrawal of approval of new animal drugs to ensure marketed products are safe and effective.
- Monitors and evaluates promotion of marketed veterinary drugs to ensure promoted claims are consistent with approved claims.
- Conducts continuing surveillance and veterinary medical evaluations of clinical experience and required reports.
- Evaluates reports of product adverse experiences to ensure labeling contains a current accurate safety profile, identifies unsafe products, and unsafe product uses. Maintains liaison with other agencies and organizations engaged in similar activities to identify product interactions and coordinate activities. Participates in outreach programs to encourage veterinarians to participate in the pharmacovigilance program.

- Manages compliance programs covering regulated industries in animal drugs, veterinary medical devices, and other veterinary medical products to ensure the effectiveness of the programs. Reviews establishment inspection reports, labeling, and other findings to determine whether regulated products are being marketed in accordance with the Federal Food, Drug, and Cosmetic Act (the Act) and Agency regulations and policy.

DIVISION OF ANIMAL FEEDS (HFV-220)

The functional statements for the Division of Animal Feeds are:

- Evaluates food additive petitions, and generally recognized as safe (GRAS) petitions and investigational food additive applications for adequacy of animal safety and utility data, active ingredient stability, labeling, and manufacturing facilities and controls; and coordinates the review of the human food safety and environmental impact information. Recommends approval to the Center Director.
- Approves medicated feed applications after being assured that the applications can manufacture and label medicated feed in compliance with Agency regulations.
- Evaluates the safety of complete animal feeds, dietary supplements, and feed ingredients and provides risk assessments on the toxic effects of contaminants of animal feed.
- Evaluates safety data, manufacturing and use information, and labeling for feeds and non-drug substances added to animal feeds to determine their legal status.
- Recommends and may participate in intramural and extramural research projects conducted or coordinated by the Office of Research to gain information on contaminants, drugs, and food additives.
- Provides technical and scientific assistance to and coordinates activities with state feed control offices and the Association of American Feed Control Officials (AAFCO) committees and task forces.
- Develops, monitors and evaluates CVM compliance programs or field assignments for medicated feeds, Type A medicated articles, and feed contaminants (mycotoxins, pesticides, heavy metals, industrial chemicals). Reports the findings from the programs to the states, FDA field, and other interested parties.

There are two branches within this division.

Feed Safety Branch
Petitions Review and Medicated Feeds Branch

DIVISION OF COMPLIANCE (HFV-230)

The functional statements for the Division of Compliance are:

- Coordinates the preparation of evidence concerning withdrawal/refusal to approve animal drugs and the documentation for a formal evidentiary hearing; coordinates the preparation of administrative and evidentiary records for a hearing.
- Develops, monitors, and evaluates the Center's Bioresearch Monitoring Programs and their investigative and regulatory follow-up. Manages the application integrity policy.
- Develops, monitors, and evaluates the Center's compliance and surveillance programs pertaining to tissue residues and National Drug Residue Milk Monitoring.
- Evaluates regulatory approaches to human food safety concerns including monitoring the

prevalence of violative levels of harmful drugs and chemicals in meat and poultry based on findings reported to FDA/CVM by USDA/FSIS and developing strategies designed to prevent food safety problems associated with pathogens and residues.

- Coordinates and prepares compliance and enforcement oriented replies to inquiries from consumers, state and federal governments, Congress, industry, etc.
- Advises on regulatory and administrative policy issues and develops enforcement strategies involving animal drugs, feeds, feed additives, veterinary medical devices, and other veterinary medical products; prepares and issues guidance to the field offices.
- Preliminarily reviews Establishment Inspection Reports, investigations, complaints and other information on regulated products. Coordinates investigative and regulatory follow-up through consultation with management, legal and scientific advisors. Reviews proposed regulatory actions submitted by the field offices and recommends whether such actions should be pursued further by the Agency.

There are two branches and one staff within this division:

Bioresearch Monitoring Program Staff
Case Guidance Branch
Petitions and Regulations Branch

1-80 ENFORCEMENT POLICY DIRECTORY

OFFICE OF REGULATORY AFFAIRS (ORA) (HEADQUARTERS)

Associate Commissioner for Regulatory Affairs (ACRA)

ACRA (HFC-1) 301-827-3101
Deputy ACRA (HFC-2) 301-827-3101

Office of Enforcement (OE)

Director, OE (HFC-200)... 301-827-0421
Deputy Director, OE (HFC-201) 301-827-0430
Director, Division of Compliance Management and Operations (HFC-210).....301-827-0406
Director, Division of Compliance Policy (HFC-230)..... 301-827-0393
Director, Division of Compliance Information and Quality Assurance (HFC-240)301-827-0386

ORA Office of Enforcement (HFC-200)..... 301-827-0421

Compliance Policy Council
Internet Regulatory Policy and Enforcement

Division of Compliance Management and Operations (HFC-210) 301-827-0406

Case Review and Management
Civil Money Penalties (Compliance)
Inspection Warrants
Recalls
Team Biologics (Compliance)
Warning Letter Database

Division of Compliance Policy (HFC-230)..... 301-827-0393

Bioresearch Misconduct and Monitoring
Good Guidance Practices (GGPs)
Information Disclosure (including FOI)
Policy (Biologics, Civil Money Penalties, Cosmetics, Drugs, Foods, Medical Devices, Veterinary Medicine)
Publications (Compliance Policy Guides Manual, Enforcement Notes, Enforcement Story, Federal Cooperative Agreements Manual, Information Disclosure Manual, International Cooperative Agreements Manual, Regulatory Procedures Manual)
Testimony

Division of Compliance Information and Quality Assurance (HFC-240)... 301-827-0386

Electronic Records and Signatures (21 CFR Part 11)
FACTS Firm Profiles (COMSTAT)
Gold Disk
Government-Wide Quality Assurance Program (GWQAP)
Quality Management Systems (QMS)

Office of Regional Operations (ORO)

Director, ORO (HFC-100) 301-443-6230

Deputy Director, ORO (HFC-101) 301-443-6230
Director, Division of Field Investigations (HFC-130) 301-827-5653
Director, Domestic Operations Branch (HFC-130) 301-827-5653
Director, International Operations Branch (HFC-130) 301-827-5653
*Director, Emergency Operations Center (HFC-160) 301-443-1240
Director, Division of Field Science (HFC-140) 301-827-7605
Director, Division of Federal/State Relations (HFC-150) 301-827-6906
Director, Division of Import Operations Policy (HFC-170) 301-443-6553

*As of October 18, 2002 Emergency Operations has been organized structurally as, Office of Emergency Operations, Office of Crisis Management, Office of the Commissioner

Office of Resource Management (ORM)

Director, ORM (HFC-10) 301-443-2175
Deputy Director, ORM (HFC-10) 301-443-2175

Office of Criminal Investigations (OCI)

Director, OCI (HFC-300) 301-294-4030
Deputy Director, OCI (HFC-300) 301-294-4030

CENTER FOR BIOLOGICS EVALUATION AND RESEARCH (CBER)

Director, Office of Compliance and Biologics Quality (HFM-600) 301-827-6196
Deputy Director, Office of Compliance and Biologics Quality (HFM-601) 301-827-6195
Director, Division of Case Management (HFM-610) 301-827-3754
Director, Division of Inspections and Surveillance (HFM-650) 301-827-6352

CBER Subject Matter Areas

Advisory Opinions
ARC Working Committee
Bioresearch Monitoring
Blood Bank Guidelines
Blood Bank Software
Blood Program
Citizens Petitions
Clinical Investigator Program
Computer Policy
Directed Assignments
Error and Accident Reports
Fatalities
Field Notification - Licensing Changes
Federal Register Notices
GLP Program
Health Fraud
HIV Home Test Kits
Human Tissue
Inspections Task Force - Bacterial Products, Viral Vaccines, Allergenics, In-Vitro Diagnostics, Monoclonals, Cytokines, Blood Components, Plasma Derivatives, Tissues
IRB Program

PDMA
Plasma Program
Recalls
Regulations
Retrospective Review of Regulations
Rulemaking
Sample Collections
Sponsor Monitor Program
Tissue Related Rulemaking

CENTER FOR DRUG EVALUATION AND RESEARCH (CDER)

Office of the Center Director (HFD-1) 301-594-5400
Regulatory Policy Staff (HFD-7)..... 301-594-5400
Office of Medical Policy (HFD-40)..... 301-594-6758
Director, Division of Marketing, Advertising and Communications (HFD-40)301-827-2828
Director, Division of Scientific Investigations (HFD-340) 301-594-0020
Office of Compliance (HFD-300)..... 301-594-0054
Director, Division of Labeling and Nonprescription Drug Compliance (HFD-310)301-594-0063
Director, Division of Manufacturing and Product Quality (HFD-320).....301-594-0093
Director, Division of Prescription Drug Compliance (HFD-330). 301-594-0101

Division of Manufacturing and Product Quality (HFD-320)... 301-594-0093

Application Integrity Policy
Aseptic Processing
Biotechnology
Bulk Drugs
CGMP Guidelines
Civil Litigation Guidance
Clinical Supplies/IND CGMP
Computer Validation
Content Uniformity
Criminal Litigation Support
Data (Application) Integrity
Dissolution
Electronic Records/Signatures (Part II)
Labeling Controls (Camps)
Laboratory Issues - Non-sterile Products, Sterile Products
Lyophilization
Medical Gases
NDA/ANDA Pre-Approval Inspections
Penicillin Cross Contamination
PET Radiopharmaceuticals
Pharmacy Compounding
Process Validation - Non-Sterile Dosage Forms, General, Sterile
Recycling Containers
Repackaging
Salvaging

Stability/Expiration Dates
Sterile Facility Construction
Sterilization Validation
Topical Drugs
Videoconferencing

Division of Prescription Drug Compliance (HFD-330)..... 301-594-0101
Adverse Drug Experience Reporting
Criminal Litigation Support
DESI
Digoxin Certification
Drug/Device Issues
Drug Quality Reporting System
Drug Product Surveillance-Quality and Forensics
Field Alert Report (NDA/ANDA)
FOI Requests – Devices, Drugs
Insulin Certification and Compliance
Insulin Regulation Revisions
Manufacturing Pharmacy
Prescription Drug Labeling Rx Compliance
Prescription Drug Marketing Act
Prescription Drug Wholesale Licensing
Prescription Drug Wrap-up
Prescription to OTC
Project Management
Tamper-Resistance Packaging and Evaluation
Therapeutic Inequivalence Action Coordination Committee (TIACC)

Division of Scientific Investigations (HFD-340)..... 301-594-0020
Bioresearch Monitoring (BIMO)
Bioequivalence/Generic Drugs
Clinical Studies/IND/CGMP
Good Laboratory Practices (GLP) Compliance Issues
Institutional Review Boards (IBRs)
Narcotic Treatment Programs
Positron Emission Tomography (PET) Radiopharmaceutical
Radioactive Agents – Diagnostic, Therapeutic
Sponsor and Monitors (Compliance Issues)

OTC Compliance Team (HFD-312)..... 301-594-1065
Acne
Alcohol Drug Products
Antacids
Anticaries
Antiemetics
Antiperspirant
Boil Ointments Compliance Issues

Case Management
Cholecystokinetics
Civil Litigation Guidance
Corn and Callous Removers
Cough/Cold
Dandruff/Seborrhea/Psoriasis
Dental Products
Diaper Rash Products Compliance Issues
Exocrine Pancreatic Insufficiency (Rx-Compliance Issues)
External Analgesics/Liniments
Fever Blister (OTC) (Internal and External Antibiotics)
Hair Growth Products
Hemorrhoidals-Compliance Issues
Hypo/Hyper phosphatemia
Ingrown Toenails
Internal Analgesics
Kits/Devices
Laxatives/Antidiarrheals
Leg Cramps (OTC)
Menstrual Drug Products
Mercury Containing Topical Antimicrobials
Nail Biting/Thumbsucking
Ophthalmics
Oral Discomfort (OTC)
Oral Mucosal
OTC Drug Labeling
Overindulgence (OTC) (Compliance Issues)
Pediculicides
Pregnancy Warning
Skin Bleaching (OTC) (Compliance Issues)
Skin Protectants/Lotions
Sleep Aids/Sedatives (Compliance Issues)
Stimulants (OTC) (Compliance)
Sunscreens (Compliance Issues)
Tamper-Resistant Packaging (TRP)
Tobacco
Toothpaste
Topical Antibiotics/Analgesics
Topical Antifungal Products
Topical Antimicrobials (Compliance Issues)
Topical Otic Products
Vaginal Contraceptives (OTC) (Compliance Issues)
Vaginal Products
Vitamin/Mineral and Hematinics
Wart Remover (OTC) (Compliance Issues)

Nontraditional Drugs Compliance Team (HFD-314) 301-594-0070

Acute Toxic Ingestion (Compliance Issues)
Anthelmintics (OTC) (Compliance Issues)
Aphrodisiacs (OTC) (Compliance Issues)
Benign Prostatic Hypertrophy
Camphorated Oil
Colloidal Silver
Cosmeceuticals
Deodorants (Internal) (OTC)
Digestive Aids
Fish Oils
Homeopathy Compliance Issues
Homeopathic Drugs
Shark Cartilage (Cancer)
Sweet Spirit of Nitre
Transdermals
Weight Control

Import/Export International Drug Compliance Team (HFD-316) 301-594-3150
Certificates of Pharmaceutical Product
Counterfeit/Drugs (Imitation-Compliance Issues)
Drug Diversion
Export/Import (Certificate for Foreign Governments)
Exports under the Federal Food, Drug, and Cosmetic Act Sections 801 & 802
Import/Import Listing
Personal Importation Issues
Policy & Advisory Opinion on Import/Export
Registration and Listing Policy (OTC)
Steroid Alternatives

CENTER FOR DEVICES AND RADIOLOGICAL HEALTH (CDRH)

Director, Office of Compliance (HFZ-300)..... 301-594-4692
Deputy Director, Office of Compliance (HFZ-300)..... 301-594-4692
Director, Promotion and Advertising Policy Staff (HFZ-302)..... 301-594-4639
Director, Division of Program Operations (HFZ-305)..... 301-594-4699
Deputy Director, Division of Program Operations (HFZ-305) 301-594-4699
Chief, Field Program Branch (HFZ-306)..... 301-594-4695
Chief, Information Processing and Office Automation Branch (HFZ-307).....301-827-4555
Director, Division of Bioresearch Monitoring (HFZ-310)..... 301-594-4718
Chief, Program Enforcement Branch I (HFZ-311)..... 301-594-4720
Chief, Program Enforcement Branch II (HFZ-312) 301-594-4723
Director, Division of Enforcement I (HFZ-320) 301-594-4586
Deputy Director, Division of Enforcement I (HFZ-320)..... 301-594-4586
Case Expert (HFZ-320) 301-594-4586
Chief, In Vitro Diagnostic Devices Branch (HFZ-321) 301-594-4588
Chief, Diagnostic Devices Branch (HFZ-322..... 301-594-4591
Chief, General Surgery Devices Branch (HFZ-323) 301-594-4595
Director, Division of Enforcement II (HFZ-330) 301-594-4611

Deputy Director, Division of Enforcement II (HFZ-330) 301-594-4611
Case Expert (HFZ-330) 301-594-4611
Chief, Dental, ENT and Ophthalmic Devices Branch (HFZ-331).....301-594-4613
Chief, OB/GYN, Gastroenterology and Urology Devices Branch (HFZ-332) ...301-594-4616
Chief, General Hospital Devices Branch (HFZ-333) 301-594-4618
Director, Division of Enforcement III (HFZ-340)..... 301-594-4646
Deputy Director, Division of Enforcement III (HFZ-340)..... 301-594-4646
Case Expert (HFZ-340) 301-594-4646
GMP and Quality Systems Expert (HFZ-340) 301-594-4648
Software Expert (HFZ-340)..... 301-594-4659
Chief, Cardiovascular and Neurology Devices Branch (HFZ-341) 301-594-4648
Chief, Orthopedic, Physical Medicine and Anesthesiology Devices Branch (HFZ-342)301-594-4659
Chief, Electronic Products Devices Branch (HFZ-343)..... 301-594-4654

CDRH Subject Matter Areas

Acoustics, Division of Enforcement III
Bioresearch Monitoring, Division of Bioresearch Monitoring
Biostimulatory (LASER), Division of Enforcement III
Case Management (Legal), Division of Program Operations
Certificates for Export, Division of Program Operations
Compliance Forms, Division of Program Operations
Computed Tomography, Division of Enforcement I
Condoms, Division of Enforcement II
Cordless Telephones, Division of Enforcement III
CRT, Division of Enforcement III
Device GMP Regulations, Office of Director, OC
Device Listing, Division of Program Operations
Electronic Muscle Stimulators, Division of Enforcement III
Export-Investigational Development and Export Certificate, Division of Program Operations
Hearing Aid Regulations, Promotion and Advertising Staff
Home Exercise Equipment, Division of Enforcement III
Imports, Office of Director, OC
Infant Monitors, Division of Enforcement III
Inspection of Medical Devices
In-vitro Diagnostic Device, Division of Enforcement I
IRB, Division of Bioresearch Monitoring
Labeling - General Medical Development, Division of Enforcement I
Labeling - In-Vitro Diagnostic Development, Division of Enforcement I
Lasers, Division of Enforcement III
Light Radiation, Division of Enforcement III
Medical Device Premarket Approval and Post Market Inspections
Mercury Vapor Lamps, Division of Enforcement III
Optical Radiation, Division of Enforcement III
Quackery/Health Fraud, Division of Enforcement I
Promotion and Advertising/Off Label Use Staff
Sterilization, Division of Enforcement I
TV, Division of Enforcement III

Ultrasound, Division of Enforcement III
Variances - Light Products, Division of Enforcement III
Video Display Terminals, Division of Enforcement III
YAG Lasers, Division of Enforcement I

CENTER FOR FOOD SAFETY AND APPLIED NUTRITION (CFSAN)

Director, Office of Field Programs (HFS-600) 301-436-2359
Special Assistant (HFS-602 301-436-2055
Director, Division of Enforcement and Programs (HFS-605) 301-436-2417
Director, Domestic Branch (HFS-636) 301-436-2415
Director, Import Branch (HFS-606) 301-436-2413
Director, Case Processing Branch (HFS-607) 301-436-2361
Director, Division of HACCP Programs (HFS-615) 301-436-2410
Director, Laboratory Quality Assurance Branch (HFH-450) 708-728-4115
Director, Regulatory Food Processing and Technology Branch (HFS-617 .. 301-436-2411
Director, Division of Cooperative Programs (HFS-625) 301-436-2439
Director, Milk Safety Branch (HFS-626) 301-436-2349
Director, Retail Food Protection Branch (HFS-627) 301-436-2350
Director, Shellfish Program Implementation Branch (HFS-628) 301-436-2439
Director, Domestic Program Branch (HFS-636) 301-436-2415
Director, Office of Cosmetics and Colors (HFS-100) 202-418-3412
Director, Division of Programs and Enforcement Policy (HFS-105) 202-401-2238
Cosmetics Programs and Regulations Branch (HFS-106) 202-418-3414
Color Certification Branch (HFS-107) 202-205-5725
Director, Office of Nutritional Products, Labeling and Dietary Supplements (HFS-800) 301-436-2373
Deputy Director, Office of Nutritional Products, Labeling and Dietary Supplements (HFS-800) 301-436-2373
Director, Division of Compliance and Enforcement (HFS-810) 301-436-2375
Dietary Supplements Branch (HFS-811) 301-436-2306
Conventional Foods and Special Nutritionals Branch (HFS-812) 301-436-1430
Director, Division of Standards and Labeling Regulations (HFS-820) 301-436-2371
Dietary Supplements Team (HFS-821) 301-436-1443
Conventional Foods Team (HFS-822) 301-436-1802
Clinical Support Team (HFS-805) 301-436-2566
Director, Division of Nutrition Science and Policy (HFS-830) 301-436-1450
Infant Formula and Medical Food Team (HFS-831) 301-436-1453
Nutrition Labeling and Programs Team (HFS-832) 301-436-1458
Clinical Support Team (HFS-805) 301-436-1444
Director, Division of Research and Applied Technology (HFS-840) 301-436-1786
Database Management and Evaluation Team (HFS-840) 301-436-1788
Methods Development and Application Team (HFS-840) 301-436-1779
Director, Office of Plant and Dairy Foods and Beverages (HFS-300) 301-436-1700
Director, Division of Plant Product Safety (HFS-305) 301-436-1400
Regulatory Policy Branch (HFS-306) 301-436-2033
Implementation and Compliance Branch (HFS-307) 301-436-2032
Director, Division of Dairy and Egg Safety (HFS-365) 301-436-2367
Regulatory Policy Branch (HFS-366) 301-436-1495

Implementation and Compliance Branch (HFS-367) 301-436-1494
Director, Division of Risk Assessment (HFS-355) 301-436-2402
Exposure Assessment Branch (HFS-357)..... 301-436-2042
Hazard Assessment Branch (HFS-356) 301-436-2402
Director, Office of Seafood (HFS-400) 301-436-2300
Deputy Director, Office of Seafood (HFS-400) 301-436-2300
Associate Director, Office of Seafood (HFS-400)..... 301-436-2300
Director, Division of Programs and Enforcement Policy (HFS-415).....301-436-2303
Director, Policy and Guidance Branch (HFS-416)..... 301-436-2303
Director, Programs and Enforcement Branch (HFS-417)..... 301-436-2303

CFSAN Subject Matter Areas

Domestic Acidified and Low-Acid Canned Foods
Domestic Fish and Fishery Products
Domestic Food Labeling and Economics
Domestic Food Safety
Domestic and Imported Soft Cheese
General Consumer Education
Import Acidified and Low Acid Canned Foods
Imported Foods - Food and Color Additives
Imported Foods - General Program
Imported Foods - Labeling and Economics
Imported Foods - Nutrition and Nutrition Labeling
Infant Formula - Import and Domestic
ITS - CSF
Medical Foods - Import and Domestic
Milk Safety Program
Molluscan Shellfish Evaluation Program
Mycotoxins in Domestic Foods
Mycotoxins in Imported Foods
National Drug Residue Milk Monitoring Program
Nutrient Content of Dietary Supplements
Pathogen Monitoring of Selected High Risk
Pesticides and Industrial Chemicals in Domestic Aquaculture Products
Pesticides and Industrial Chemicals in Imported Foods
Processed Seafood Program
Radionuclides in Foods
Retail Food Protection - Federal
Retail Food Protection - State
Total Diet Study
Toxic Elements in Tableware/Cookware - Import & Domestic

Analytical Methods

Amnesic Shellfish Poison
Chemical Contaminants
C. botulinum
Color Additives

Decomposition
E. coli
E. coli (enterotoxigenic)
E. coli (enterohemorrhagic) 0157:H7
Filth Analysis
Food Additives
Listeria Monocytogenes
Listeria gene probe
Microbiological Analysis
Molecular Biology and Natural Toxins
Parasite Analysis
Paralytic Shellfish Poison Phosphatase
Scallop Moisture Content
Species Substitution
Staphylococcus aureus
Staphylococcus Enterotoxin
Salmonella
Yersinia enterocolitica
V. cholerae
V. cholerae PCR Methodology
V. parahaemolyticus
V. vulnificus

CENTER FOR VETERINARY MEDICINE (CVM)

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CVM Subject Matter Areas

Pre-Approval Inspections - NADA
Drug Process and New Animal Drug Inspections
Illegal Sales of Veterinary Prescription Drugs
Feed Contaminants Program

Medicated Feeds
Type A Medicated Articles

Office of Surveillance and Compliance (HFV-200)..... 301-827-6644
Animal Health Fraud
Aquaculture/Seafood HAACP
Assignment Tracking
Bulk Drugs
Contaminant Response System
Counterfeiting
Drug GMPs
Federal/State Relations
Fermentation Products
HACCP
Homeopathics
Illegal Distribution of Rx Drugs
Imports
LACF
Medicated Feeds
Milk
Mycotoxins
National Antimicrobial Resistance Monitoring System (NARMS)
New Animal Drug Determination
Poison Antidotes
Recalls
Salmonella
Tissue Residue
Veterinary Biologics
Veterinary Devices and Diagnostics
Extra Label Use of Drugs in Animals

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